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Filed : January 25, 2002

### REMARKS

The changes made to the Specification and Claims by the current amendment, including ~~deletions~~ and additions, are shown herein with deletions designated with a strikethrough and additions underlined. Claim 89 has been amended to correct the dependency. The specification has been amended to include the priority information.

#### Response to Office Communication mailed 10/14/2003

The response dated 10/14/2003 from the United States Patent and Trademark Office states that the previously filed amendment (August 1, 2003) failed to comply with the requirements set forth in the Notice of Non-Compliant Amendment, mailed on July 16, 2003, because it failed to provide a copy of claims 216-221. Further, the response dated 10/14/2003 did not reset the time for reply, but continued to run from the date of the Notice of Non-Compliant Amendment. Applicants have corrected the omission of Withdrawn Claims 216-221 herein and paid the extension fees as required. However, Applicants respectfully disagree with the decision to disallow a reset time for reply.

MPEP 714.03 states in column two paragraph two that: "Where an amendment substantially responds to the rejections, objections, or requirements in a non-final Office action (and is a bona fide attempt to advance the application to final action) but contains a minor deficiency (e.g., fails to treat every rejection, objection, or requirement), the examiner may simply act on the amendment and issue a new (non-final or final) office action." (underlining added).

Applicants respectfully request the Examiner to note that the previously filed Amendment was submitted before the first deadline and was necessary purely to conform the response to the revised amendment format during the first week of mandatory compliance. The omission of 6 claims which were withdrawn can be considered a minor deficiency and did not affect the ability of the Examiner to substantially examine the pending claims (since withdrawn claims are not pending). Thus, Applicants respectfully request the Examiner re-evaluate the necessity for the present Office Communication and the decision to waive a reset time for reply. Applicants further respectfully request the Examiner to reevaluate the Extensions incurred as a result.

#### Restriction Requirement

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In response to the telephonic restriction requirement of March 13, 2003, Applicants elected Invention III, Species I, Claims 1, 39, and 75-104. Upon allowance of the elected claims, Applicants respectfully request rejoinder of dependent claims 2-38 and 40-74 as being dependent upon an allowed independent claim.

**Rejection under 35 U.S.C. §102(b)**

The Examiner has rejected Claims 1 and 75 as being anticipated by Kelman USPN 4,268,921, hereinafter referred to as Kelman '921. However, Applicants submit that Kelman '921 does not anticipate the claimed invention because the IOL of Kelman '921 does not include a haptic with: "at least one "V"-shaped element having a pair of legs and a square or rounded corner; and at least two contact points for the eye each located on one of said legs or one of said corners"

The IOL of Kelman '921 has 3 distinct support members (legs) or 3 "haptics", two of which (18 and 20) are integrally joined to the lens (column 3, lines 22-25 of Kelman '921) and a third support member (leg) 42 which is attachable by means of an external thread and a lens recess with an internal thread. As evidenced by the Declaration of Dr. Charles Kelman, the inventor of the '921 patent, and as evidenced by the enclosed Exhibit A, the use of the term "haptic" specifies a single support apparatus separate from the optic. When there is more than one support member, these are referred to as "haptics" (plural) or equivalent plural terms such as "support members", "filaments", etc. Support for this statement can be found in Exhibit A which contains multiple references with examples showing that one haptic is referred to in the singular and several haptics are referred to in the plural. The IOL of Kelman '921 has an optic and 3 "haptics" (plural). Thus, it is not "a haptic" and it is not "a haptic which comprises a "V"-shaped element", because to be considered "V"-shaped, one would have to use two haptics and part of the optic to create the square or rounded corner.

With reference to Claim 75, the method of inserting the IOL of Claim 1 into the eye, Kelman '921 does not teach the IOL of Claim 1, and even if it did, it does not teach inserting the haptic separately from the optic. Kelman '921 teaches first inserting the optic plus the two haptics 18 and 20 which are integrally joined to the optic (called the lens component 44), and then inserting the third haptic 32 (see column 3, lines 16-31) and attaching it to the lens component. Thus, the optic and haptic are not inserted separately.

Thus, Kelman '921 does not anticipate the claimed invention because Kelman '921 does not teach "a haptic", "at least one "V"-shaped element", "a square or rounded corner", and "at least two contact points" on the haptic. Further Kelman '921 does not teach a haptic which is separately insertable from the optic.

**Rejection under 35 U.S.C. §103(a) - Claims 39, 87, 90, 92, 93, and 102**

The examiner has rejected Claims 39, 87, 90, 92, 93, and 102 under 35 U.S.C. §103(a) as being unpatentable over Kelman '921 in view of Simcoe (GB 2,171,912). Applicants submit that Kelman '921 does not render the claimed invention obvious because Kelman '921 in combination with Simcoe does not teach a haptic with: "two "V"-shaped elements, a separate optic; and an attachment for said optic which permits said optic to be attached to said haptic within the eye."

The IOL of Kelman '921 has 3 distinct support members (legs) or 3 "haptics", two of which (18 and 20) are integrally joined to the lens (column 3, lines 22-25 of Kelman '921) and a third support member (leg) 42 which is attachable by means of an external thread and a lens recess with an internal thread. As evidenced by the Declaration of Dr. Charles Kelman, the inventor of the '921 patent, and as evidenced by the enclosed Exhibit A (see the explanation in the response to the 103 rejection above). The use of the term "haptic" specifies a single support apparatus separate from the optic. The IOL of Kelman '921 has an optic and 3 "haptics" (plural). Thus, it is not a "haptic" and it is not a "haptic" which comprises two "V"-shaped elements, because to be considered "V"-shaped, one would have to use two haptics and part of the optic to create the square or rounded corner.

*Prima facie* obviousness requires that the combination of prior art references teach all of the claimed elements. However, the IOL of Kelman '921 does not teach all of the claimed elements because it does not have "a haptic", "a V-shaped element", or "a corner". Further, Simcoe (GB 2,171,912) does not teach a "haptic", but, like Kelman '921, Simcoe teaches "two haptics" (plural) and only teaches a one-part IOL. Thus, Simcoe does not provide the missing claim elements and the combination of Kelman '921 and Simcoe does not render the claimed invention obvious.

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**Rejection under 35 U.S.C. §103(a) - Claims 76-81, 83, 86, 91, 94-96, 98, and 101, all dependent on Claim 75**

The Examiner has rejected Claims 76-81, 83, 86, 91, 94-96, 98, and 101 as being unpatentable over the primary reference, Kelman '921 in view of a variety of secondary references. All of these Claims are dependent on Claim 75. The Examiner believes that Kelman '921 teaches a method of introducing the claimed IOL into an eye by inserting the haptic separately from the optic, as claimed in Claim 75. Applicants disagree for the following reasons: Kelman '921 does not teach the IOL of Claim 1, and even if it did, it does not teach inserting the haptic separately from the optic. Kelman '921 teaches first inserting the optic plus the two haptics 18 and 20 which are integrally joined to the optic (called the lens component 44), and then inserting the third haptic 32 (see column 3, lines 16-31) and attaching it to the lens component. Thus, the optic and haptic are not inserted separately.

Thus, since the primary reference does not teach all of the claimed elements and, in fact does not even provide the insertion of the optic separately from the haptic, the secondary references would need to teach this missing element to render the claims obvious. The secondary references do not provide the missing element and, thus, the combination of the primary reference Kelman '921 with any or all of the secondary references does not render any of the cited claims obvious. A more detailed analysis of the secondary references follows:

With respect to Claim 76, the Examiner believes that the combination of Kelman '921 and Kelman '938 teaches a method for introducing a multi-component intraocular lens that includes bending the legs toward one another to create smaller dimensions for easy implantation. However, as explained above, Kelman '921 does not teach a method of inserting a haptic separately from an optic and Kelman '938 teaches only a two part IOL, each part of which includes half of the haptic and half of the optic. In fact, the Kelman '938 IOL appears to be split in half down the middle of the optic. Kelman '938 does not teach or suggest inserting the IOL separately from the optic. Thus, Kelman '938 does not provide the missing claim elements and the combination of Kelman '921 and Kelman '938 does not render the claimed invention obvious.

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With respect to Claims 77 and 78, the Examiner submits that it would have been an obvious variation to introduce the haptic prior to the optic (or vice versa). However, since Kelman '921 does not teach inserting the haptic separately from the optic, it would not have been an obvious variation.

Claims 79 and 86 teach the additional steps of respectively, removing the optic and/or replacing it (Claim 79), and a "soft" optic made of a lower modulus material (Claim 86). The cited secondary reference Koziol teaches only a method of removing an optic and/or replacing it from a housing formed in the IOL and that the optic may be made of a "soft" material. Thus, Koziol does not provide the missing claim elements.

With respect to Claims 80 and 81 which are rejected in view of the secondary references of Koziol USPN 4,878,910 (Koziol '910) and Anello et al USPN 5,984,962 (Anello '962). Koziol teaches only a method of removing an optic from a housing in the IOL and/or replacing it and that the optic may be made of a "soft" material. Anello teaches only a method of adjusting a one-part IOL within the eye to change the focus. However, the IOL of Anello et al is a one-part IOL completely unlike that presently claimed. Thus, Koziol and Anello et al. do not provide the missing claim elements.

With respect to Claim 83, the secondary reference, Patel USPN 5,366,502 teaches only of a primary IOL which can have a supplementary IOL added to it for correction of changes after the healing of the first implantation and does not teach the claimed two-part IOL. Thus, Patel et al does not provide the missing claim elements.

With respect to Claim 91 which is rejected in view of the secondary references Simcoe GB 2,171,912 and Kelman (USPN 4,451,938), Simcoe teaches only a one-part IOL which has a flexible hinged region and Kelman '938 teaches only a two part IOL, each part of which has a half of the haptic and half of the optic. In fact, the IOL taught in Kelman '938 appears to be split in half down the middle of the optic. Kelman '938 does not teach or suggest inserting the IOL separately from the optic. Thus, Kelman '938 does not provide the missing claim elements and

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the combination of Kelman '921, Simcoe, and Kelman '938 does not render the claimed invention obvious.

With respect to Claims 94 and 101, rejected as unpatentable over Kelman '921 in view of Simcoe GB 2,171,912 and further in view of Koziol (USPN 4,878,910), Simcoe teaches only a one-part IOL with haptics formed of hinged portions made of highly flexible material. Koziol teaches only a method of removing a lens from its housing. Thus, Simcoe and Koziol et al. do not provide the missing claim elements.

With respect to Claims 95 and 96 which were rejected over the secondary references Simcoe GB 2,171,912, Kelman (USPN 4,451,938) and Anello et al (USPN 5,984,962) Anello teaches only a method of adjusting a one-part IOL within the eye to correct for astigmatism. As mentioned above, Kelman '938 does not provide the missing claim elements. Thus, Kelman '938, and Anello et al. do not render the claimed invention obvious.

With respect to Claim 98 which is rejected in view of the secondary references, Simcoe GB 2,171,912, and Patel (USPN 5,366,502), as mentioned above, neither the IOL of Simcoe nor the IOL of Patel et al provides the missing claim elements.

Thus, none of the secondary references alone or in combination with Kelman '921 teach the insertion of the haptic separately from the optic and none of the secondary references teach the haptic of Claim 1. In view of this, the combination of Kelman '921 with any or all of the secondary references does not render the cited claims obvious because they do not teach all of the claimed elements.

### **Conclusions**

The applicant has endeavored to address all of the Examiner's concerns as expressed in the outstanding Office Action. Accordingly, arguments in support of the patentability of the pending claims set are presented above. In light of these remarks, reconsideration and

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withdrawal of the outstanding rejections is respectfully requested. If the Examiner has any further questions, please contact the undersigned at the telephone number appearing below.

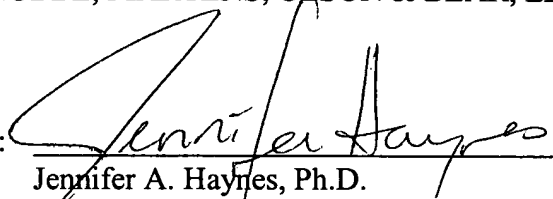
Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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Dated: Oct. 31, 2003

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